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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/656,668	09/07/00	XU	J 210121.484C3

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HM22/0410

EXAMINER	
ZEMAN, M	
ART UNIT	PAPER NUMBER
1631	5

DATE MAILED: 04/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/656,668	XU ET AL.	
	Examiner	Art Unit	
	Mary Zeman	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-65 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims 1-65 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 9-12, 21, 23, and 24 drawn to isolated polypeptides, classified in class 530, subclass 300 and class 514, subclass 2+.

II. Claims 3-8, 13-16, 22, 25, 26 and 65, drawn to isolated polynucleotides, vectors, transformed host cells, classified in class 536, subclass 24.1, and class 435, subclass 320.1 and class 514, subclass 44.

III. Claims 17 and 60-64, drawn to antibodies to polypeptides and kits comprising those antibodies, classified in class 530, subclass 388.1.

IV. Claims 18-20, 27 and 28, drawn to a method of inhibiting cancer with a polypeptide, classified in class 514, subclass 12.

V. Claims 18-20, 27 and 28, drawn to methods of inhibiting cancer with a polynucleotide, classified in class 514, subclass 44.

VI. Claims 18-20, drawn to methods of inhibiting cancer with an antibody, classified in class 424, subclass 130.1.

VII. Claims 29, 30 and 32, drawn to an antigen presenting cell, classified in class 424, subclass 93.7.

VIII. Claims 31 and 32, drawn to anti-idiotype antibodies, classified in class 424, subclass 130.1.

IX. Claims 33 and 34, drawn to a specifically reacting T cell, classified in class 424, subclass 93.71.

X. Claims 35 and 36, drawn to methods of inhibiting cancer by administering an antigen presenting cell, classified in class 435, subclass 93.7.

XI. Claim 36, drawn to methods of inhibiting cancer by administering an anti-idiotype antibody, classified in class 424, subclass 131.1.

XII. Claims 35, 36 and 41, drawn to methods of inhibiting cancer by administering a specifically reactive T cell, classified in class 435, subclass 93.71.

XIII. Claims 37-40, drawn to methods of stimulating T cell expansion by administering a polypeptide or polynucleotide, classified in class 424, subclass 184.1.

XIV. Claims 42-45 , drawn to methods of inhibiting cancer in a patient through ex vivo T cell stimulation, classified in class 435, subclass 2, and subclass 455.

XV. Claims 46-49, drawn to peptide based methods of diagnosing cancer, classified in class 435, subclass 7.1.

XVI. Claims 50-53, drawn to peptide based methods of monitoring cancer progression, classified in class 435, subclass 7.7.

XVII. Claims 54-56, drawn to hybridization based methods of diagnosing cancer, classified in class 435, subclass 91.1.

XVIII. Claims 57-59, drawn to hybridization based methods of monitoring progression of cancer, classified in class 435, subclass 91.2.

The inventions are distinct, each from the other because of the following reasons:

. Inventions I and II are separate and distinct because the inventions are directed to different chemical types regarding the critical limitations therein. For Group I, the critical feature is a polypeptide whereas for Group II the critical feature is a polynucleotide. It is acknowledged that various processing steps may cause a polypeptide of group I to be directed as to its synthesis by a polynucleotide of Group II, however, the completely separate chemical types of the inventions of Groups I and II supports the undue search burden if both were examined together. Additionally, polypeptides have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examiner together, as compared to being searched separately. Also, it is pointed out that processing that may connect two groups does not prevent them from being viewed as distinct, because enough processing can result in producing any composition from any other composition if the processing is not so limited to additions, subtractions, enzyme actions, etc.

Inventions I and IV, XIII, XV and XVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides can be used in a method of purifying serum antibodies to the antigens through immunoaffinity chromatography.

Inventions II and V, XIII, XVII and XVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides can be used in expression profiles for cancerous cells.

Inventions I/II and III are separate and distinct, as the claims of Invention I/II are drawn to polynucleotides and polypeptides, while the claim of group III is drawn to an antibody. These are differing biochemical entities having differing biochemical properties, structures and effects. Invention III would require searching in areas unrelated to polynucleotides and polypeptides, and as such, would require an undue burden on the examiner if not restricted.

Inventions I-III are separate and distinct from the differing cells of Inventions VII and IX. These are differing biochemical entities having differing biochemical properties, structures and effects. The Inventions would require searching in unrelated areas, and as such, would require an undue burden on the examiner if not restricted.

Inventions III and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies can be used in an antibody-based ELISA for detection of the proteins.

The antibodies of Invention III are separate and distinct from the anti-idiotype antibodies of Invention VIII as they bind differing polypeptides and have differing intended uses. The Inventions would require searching in unrelated areas, and as such, would require an undue burden on the examiner if not restricted.

The APC's of Invention VII are separate and distinct from the specific T cells of Invention IX as they are differing cell types having differing activities, and differing biological and biochemical properties. The Inventions would require searching in unrelated areas, and as such, would require an undue burden on the examiner if not restricted.

Each of the methods of inhibiting cancer of Inventions IV-VI, X-XII and XIV are separate and distinct from one another, as they use differing products in the treatment or prevention of a cancer in a patient. Each of the particular compositions being used in the listed inventions have differing biological properties (reflected in the above Restriction Requirement), and effects, such that the efficacy of one method does not speak to the efficacy of a method using a differing composition. The Inventions would require searching in unrelated areas, and as such, would require an undue burden on the examiner if not restricted.

The method of Invention XIII is separate and distinct from all other groups as it is drawn to methods of T cell stimulation in vitro, which would require search and considerations not needed for any of the other groups.

Inventions XV-XVIII are all separate and distinct from one another as they are differing methods having differing steps using differing reagents to differing ends. The Inventions would require searching in unrelated areas, and as such, would require an undue burden on the examiner if not restricted.

Sequence Election Requirement Applicable to All Groups

In addition, each Group detailed above reads on patentably distinct Groups drawn to multiple SEQ ID Numbers. The sequences are patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid sequences, the Applicants must further elect a single amino acid sequence. For an elected group drawn to an antibody, Applicants must elect a single antigen to which the antibody binds. For an elected Group drawn to nucleotide sequences, the Applicants must elect a single nucleic acid sequence (See MPEP 803.04).

Applicant is requested to amend the claims to be commensurate in scope with the elected sequence.

MPEP 803.04 states:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37

CFR 1.141 et seq. Under the present circumstances, it has been determined that the search and examination of more than one unrelated nucleotide sequence would pose an undue burden upon the Office resources and the examiner. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

A fully responsive communication will contain both a proper election of a group, and a further sequence election, as required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133. The examiner can be reached between the hours of 7:30 am and 5:00 pm Monday through Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308 4028.

The fax number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center receptionist whose telephone number is (703) 308-0196.

Mary K Zeman

MARY K. ZEMAN
PATENT EXAMINER

mkz
April 5, 2001

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